




**Homopolymer
Interim Registration Review Decision
Case Number 5024**

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Approved by:



Steve Knizner
Director
Antimicrobials Division

Date:

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Homopolymer Registration Review Team

Human Health & Environmental Effects

Siroos Mostaghimi

Jim Breithaupt

David Bays

Jonathan Chen

Nate Mottl

Katelynn King

Risk Management

Donna Kamarei

Rose Kyprianou

Office of General Counsel

Philip Ross

TERMS, ABBREVIATIONS AND SYMBOLS

AD	Antimicrobials Division
A.I. or a.i.	active ingredient
ASRI	activated sludge respiration inhibition
CAS	Chemical Abstracts Service
CFR	Code of Federal Regulations
CMA	Chemical Manufacturers Association
COC	concentration-of-concern
EC ₅₀	median (or 50 percent) effect concentration
ECOTOX	ECOTOXicology
EDSP	Endocrine Disruptor Screening Program
E-FAST	Exposure and Fate Assessment Screening Tool
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
HPV	high production volume
IDS	Incident Data System
K _{ow}	octanol-water partition coefficient
LC ₅₀	median (or 50 percent) lethal concentration
LD ₅₀	median (or 50 percent) lethal dose
Log K _{ow}	logarithm of the octanol-water partition coefficient
µg	microgram
mg/kg	milligram per kilogram
mg/L	milligram per liter
mm Hg	millimeter of mercury
MRID	Master Record Identification Number
MRL	maximum residue limit
N/A	not applicable
nm	nanometers
NOAEC	no-observed-adverse-effect-concentration
OCSPP	Office of Chemical Safety and Pollution Prevention
OPP	Office of Pesticide Programs
%	percent
PC Code	Pesticide Chemical Code
pKa	power of the acid dissociation constant or negative base-10 logarithm of the acid dissociation constant of a solution
ppb	parts per billion
ppm	parts per million
PWP	Preliminary Work Plan
RED	Reregistration Eligibility Decision
SSTS	Section Seven Tracking System
TGAI	technical grade active ingredient
TMDL	total maximum daily loads
UV/VIS	ultraviolet/visible light absorption
WWTPs	wastewater treatment plants

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1 Introduction

This document is the Environmental Protection Agency's (EPA or "the agency") Interim Registration Review Decision for 2-Propen-1-aminium, N,N-dimethyl-N-2-propenyl-, chloride, homopolymer herein referred to as homopolymer, and is being issued pursuant to 40 CFR Sections 155.50, 155.56 and 155.58. This document explains what EPA's Office of Pesticide Programs knows about homopolymer, noting that no additional data nor further assessments are required, and provides an anticipated timeline for completing homopolymer's review.

A registration review decision is the agency's determination whether a pesticide meets, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review.

The Proposed Interim Registration Review Decision for homopolymer was issued for public comment on August 10, 2015 and the comment period closed on October 9, 2015. During the 60-day public comment period, no comments were received concerning the registration review of homopolymer. As a result, no changes were made to the document.

1.1 Statutory and Regulatory Authority

The Food Quality Protection Act (FQPA) of 1996 mandated a registration review program. All pesticides distributed or sold in the United States generally must be registered by the USEPA based on scientific data showing that they will not cause unreasonable risks to human health or the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided at <http://www2.epa.gov/pesticide-reevaluation>.

The agency is implementing the registration review program pursuant to Section 3(g) of FIFRA and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The regulations governing registration review begin at 40 CFR 155.40. The agency will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision.

1.2 Case Overview

The docket for homopolymer (case # 5024) has been established at <http://www.regulations.gov> in docket number EPA-HQ-OPP-2015-0255. Documents associated with this registration review can be viewed in this docket. Tables 1-2 below summarize the issues relevant to this registration review case and the anticipated registration review schedule.

Table 1 – Summary of Anticipated Risk Assessments and Data Needs for Registration Review: Homopolymer

Risk Assessment	Assessment Necessary to Support Registration Review	Date of Most Recent Assessment	Type of Assessment Required (New/Updated)	Data Anticipated as Needed
Dietary (food/ drinking water)	No	N/A	None	None
Occupational & Residential Handler/Post Application	No	N/A	None	None
Aggregate	No	N/A	None	None
Cumulative	No	N/A	None	None
Tolerance Review	No	N/A	None	None
Ecological	No	N/A	None	None

N/A = Not applicable

Table 2 – Anticipated Registration Review Schedule

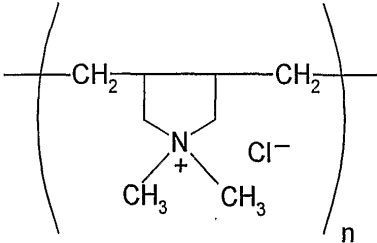
Anticipated Activity	Target Date*	Completion Date
Combined Preliminary Work Plan and Interim Registration Review Decision and Implementation		
Open 60-Day Public Comment Period for Combined Preliminary Work Plan and Proposed Interim Decision	2015-06	2015-08-10
Close Public Comment Period	2015-08	2015-10-09
Issue Interim Decision and Begin Post-Decision Follow up*	2015-12	
Total (years)	1	

* A final decision on the homopolymer registration review case, in accordance with 40 CFR Section 155.58, will occur after an EDSP FFDCA section 408(p) determination has been made.

1.3 Chemical Identification and Properties

Table 3 presents the active ingredient to be assessed in case 5024: homopolymer (PC Code 128727). The active ingredient has one registered product with the active ingredient composing 19.8 percent (w/w).

Table 3 – Chemical Identification of Homopolymer

Chemical Name	Homopolymer	Reference (MRID unless specified) Comments
Chemical Classification	Polymeric quaternary ammonium	PAN ¹
PC Code	128727	None
CAS Number	26062-79-3 (polymer) 7398-69-8 (monomer)	PAN
Molecular Formula	Polymer: Not applicable Monomer: C ₈ H ₁₆ CN	None
Molecular Weight (grams/mole)	200,000 (average, polymer) 161.68 (monomer)	Sigma Aldrich (polymer) Epi-Web 4.1 (monomer)
Molecular Structure		Hess et al., 2003

The homopolymer physical chemistry information is summarized in Table 4. The details of the environmental fate information are discussed in Appendix B.

Table 4 – Physical-Chemical and Environmental Fate Properties for Homopolymer

Guideline No.	Parameter	Homopolymer (EPA Reg. No. 1706-226): Poly (dimethyldiallyl) ammonium chloride	Reference (MRID unless specified)
830.7050	UV/Visible Absorption	Stable to sunlight (no conjugation in structure)	Lyman et al., 1990
830.7370	Dissociation constant (pKa)	Not applicable	No ionizable functional groups
830.7550	Octanol-water partition coefficient at 25 °C (Log K _{ow})	Not applicable (substance is miscible in water)	42618401
830.7840	Solubility in water	Miscible (10,000 mg/l used in calculations)	42618401
830.7950	Vapor pressure (mmHg)	Polymer: None (up to 230 °C) Monomer: 15 mm Hg	42618401
None	Henry's law constant at 25 °C (atm-m ³ /mol) CALCULATED	Polymer: Not applicable (polymer has wide range of molecular weights) Monomer: 3.2 x 10 ⁻⁴	None

atm-m³/mol = atmosphere cubic meter per mole; °C = degrees Celsius; mg/L = milligrams per liter; mmHg = millimeters of mercury.

¹ http://www.pesticideinfo.org/Detail_Chemical.jsp?Rec_Id=PC35969

1.4 Use/Usage Description

1.4.1 Registrations

There is one EPA-registered product containing homopolymer as an active ingredient (a.i.).² It contains 19.8 percent homopolymer in a liquid soluble concentrate formulation.

1.4.2 Summary of Registered Uses

Table 5 presents the registered use of homopolymer as mollusk control (e.g. Zebra mussels) in potable water supplies. The product is added to water systems as a concentrated liquid using metered pumps. The label states that applications should occur at a point sufficiently inside the intake pipe to prevent any release of product into the intake source (5-10 feet). Feed exits must be equipped with a pressure check valve at the feed line exit to seal the feed line when the intake flow stops. Feed pumps must be designed to shut down when intake pumps stop. Planned shutdowns require feed pumps to be stopped half an hour prior to shut down.

Table 5 – Homopolymer Registered Use

Use	Application Method	Application Rate (ppm a.i.)
Industrial Process and Water Systems		
Water supplies	Metered Pump	25-50

1.4.3 Usage Information

In addition to its use as a pesticide, homopolymer is used as a flocculant in drinking water treatment. Based on information provided by the registrant, the pesticidal use of homopolymer is minor when compared to the non-pesticidal use. According to the 2004 high production volume test plan, homopolymer has been manufactured for at least 40 years in the United States with three current manufacturing facilities. The monomer is used almost exclusively in the manufacturing of cationic, water-soluble polymers which are used in such industries as water treatment plants, paper mills, and textile printing. Using Best Available Technology (BAT) to achieve maximum efficacy, the maximum free monomer content of the polymeric products is about 1 percent.³

1.5 Regulatory History

The first product containing homopolymer was registered on October 6, 1995 for the use in industrial process and water systems. A Reregistration Eligibility Decision (RED) was not completed for homopolymer because it was registered after November 1, 1984.

² Veligon TL-M, EPA Reg. No. 1706-226

³ Regnet Environmental Services

1.5.1 Recent/Pending Regulatory Actions

There are no recent regulatory actions for homopolymer.

1.5.2 Tolerance Information

There are no EPA-established tolerances in raw agricultural commodities or processed food and feed products for homopolymer under the Federal Food, Drug and Cosmetic Act (FFDCA) Sections 408. Additionally, the Federal Food and Drug Administration (FDA) has not established any clearances under FFDCA 409. However, Food Contact Notifications (FCNs) have been established for homopolymer as part of various polymers. Since these uses are not FIFRA-registered, no dietary exposure assessment is required.

1.6 Incidents

1.6.1 Human Health

No homopolymer related incidents have been reported in the agency's Incident Data System (IDS) for the time period from 1992 to present, based on a search conducted on March 2015. IDS contains reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992.

1.6.2 Ecological

No homopolymer incidents have been reported in the agency's Ecological Incident Information System (EIIS) for the time period spanning 2000 to 2015 based on a search conducted on April 15, 2015.

2 Anticipated Data Needs

The agency does not anticipate requiring any additional data to support this registration review.

3 Human Health Risk Assessment

With the existing toxicology database, homopolymer appears to have low toxicity (Appendix A). The use of homopolymer as a water treatment for control of mollusks in water supplies is not expected to pose a hazard to food or drinking water based on the lack of exposure. The application system is closed and there is no expected occupational exposure. The agency does not anticipate the need to conduct a human health risk assessment for homopolymer.

3.1 Existing Toxicological Endpoints

No toxicological endpoints have been selected for homopolymer.

3.2 Dietary Exposure

The agency does not anticipate the need to conduct a dietary exposure assessment to support this registration review.

3.2.1 Food and Drinking Water

A dietary (food and drinking water) exposure assessment is not required for homopolymer. The only FIFRA-registered use of homopolymer is as a water treatment for the control of mollusks in water supplies. There is only one label use for this product, and this use is not expected to result in direct or indirect dietary (food) exposure. The use of homopolymer as a water treatment for the control of mollusks in water supplies is not expected to result in exposure from groundwater or surface waters; therefore, a drinking water assessment is not required.

3.3 Occupational and Residential Exposures

In April of 2015, the registrant amended its label to restrict application to closed metered delivery systems; open pouring is prohibited for water treatment. Occupational handler exposures are not expected due to closed mixing/loading. Dermal and inhalation post-application exposures for the water treatment uses are expected to result in limited exposure contact. No additional occupational exposure data or occupational risk assessments are anticipated to be required. No residential exposure is expected since applications are only performed in occupational settings.

3.4 Aggregate and Cumulative Exposure

3.4.1 Aggregate Exposures

An aggregate exposure risk assessment will not be conducted for this chemical because of a lack of residential exposure due to its use pattern of only being applied in industrial pipes with restrictions for controlling backflow into surface water.

3.4.2 Cumulative Exposures

With respect to cumulative exposure, unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to homopolymer and any other substances, and homopolymer does not appear to produce a toxic metabolite produced by other substances. For the purposes of this registration review, therefore, EPA has not assumed that homopolymer has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

4 Environmental Risk Assessment

The agency has not previously conducted a risk assessment that supports a complete endangered species determination for homopolymer. The label states that application to intake water should be made 5-10 feet away from the source water intake source to prevent contamination. Based on the use in potable water supply systems, the potential pathways of exposure to aquatic organisms include transport from in-service use to surface water by way of wastewater treatment plants (WWTPs) and any backflow from treated intake water. However, label restrictions prevent backflow into surface water, and the environmental fate data indicate strong sorption to sediment.

Based on the chemical, physical, and environmental fate properties, homopolymer is miscible in water, non-volatile, and stable to hydrolysis and photodegradation. Environmental fate data are not anticipated to be required (Table 4 and Appendix B). The acceptable activated sludge respiration inhibition (ASRI) study (MRID 49437513) demonstrated an IC₅₀ of 127 mg/L (>20 mg/L) indicating negligible effects on WWTP organisms.⁴ While data on sorption to soil and sediment (835.1230) have not been submitted, the agency considers drinking water exposure to be negligible because, as a quaternary ammonium polymer, homopolymer will attach to suspended sediments and organic matter and will be removed by flocculation and coagulation of suspended particles in source water. Flocculants work by reducing or neutralizing negative charges on suspended particles, allowing them to associate and settle in the treatment process.⁵ If any particles with sorbed homopolymer are redeposited into surface water, homopolymer is not expected to desorb and enter the water column. The agency does not intend to conduct an environmental risk assessment because label restrictions prevent backflow into surface water.

4.1 Threatened and Endangered Species

There is no reasonable expectation for the registered use of homopolymer to cause direct or indirect adverse effects to threatened and endangered species. No adverse modification of any designated critical habitat for such species is expected from the use of homopolymer. Exposure of terrestrial species is unlikely, because label restrictions prevent backflow into surface water, and the environmental fate data indicate strong sorption to sediment. EPA has made a “no effect” determination under the Endangered Species Act (ESA) for all listed species and designated critical habitat for such species and has therefore concluded that consultation with the Fish and Wildlife Service and the National Marine Fisheries Service under ESA section 7(a)(2) is not required.

4.2 Environmental Fate Assessment

Based on the chemical, physical, and environmental fate properties, homopolymer is miscible in water, non-volatile, and stable to hydrolysis and photodegradation (Table 4 and Appendix B).

⁴ Breithaupt, James; D427116, Reviewed and accepted on May 5, 2015

⁵ CIBA, http://www.siltstop.com/pdf/flocculation-theory_application.pdf

Additional environmental fate data are not required because backflow into surface water is not expected to occur based on the use directions specified on the label.

4.2.1 Water Quality

Homopolymer is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act.⁶ In addition, no Total Maximum Daily Loads (TMDL) have been developed for homopolymer.⁷ More information on impaired water bodies and TMDLs can be found at EPA's website.⁸

4.3 Conceptual Models for Environmental Exposure Pathways

The only environmental exposure pathway for the pesticidal use of homopolymer is one of potential backflow into the surface water used as source water. As a mitigation measure, the labels state that application to intake water should be made 5-10 feet away from the source water intake source to prevent contamination. As a result, the agency assumes that no environmental exposure will occur and therefore is not including conceptual models for exposure.

4.4 Ecological Effects Assessment

An ecological effects risk assessment is not required for this chemical because of a lack of exposure to non-target organisms due to its restricted use pattern of only being applied in industrial pipes with restrictions for controlling backflow into surface water.

4.4.1 Measures of Effect (Ecotoxicology Endpoints)

Ecotoxicity endpoint data are used as measures of effects to aquatic and terrestrial organisms. Selected endpoints are not necessary for this chemical because an environmental risk assessment is not necessary. There were six ecotoxicity studies submitted to the agency as a condition of registration for two chemicals containing homopolymer as an active ingredient. These studies are outlined in Appendix C.

4.5 Exposure Analysis Plan

4.5.1 Aquatic and Terrestrial Wildlife Exposure Estimates

The agency does not need to conduct an ecological risk assessment because of negligible environmental exposure based on the label language to prevent backflow from intake pipes and the strong tendency of homopolymer to sorb to negatively-charged particles in intake water.

⁶ http://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=885

⁷ http://iaspub.epa.gov/tmdl_waters10/attains_nation.tmdl_pollutant_detail?p_pollutant_group_id=885&p_pollutant_group_name=PESTICIDES

⁸ <http://www.epa.gov/owow/tmdl/>

4.5.2 Screening Level Down-the-Drain Analysis

The Down-the-Drain (DtD) module of E-FAST (Exposure and Fate Assessment Screening Tool) was not used to assess homopolymer since the compound is a strong flocculant which would be removed prior to a wastewater treatment plant.

5 Endocrine Disruptor Screening Program (EDSP)

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision, for homopolymer, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), homopolymer is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a “naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.” The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013⁹ and includes some pesticides scheduled for registration review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website.¹⁰

⁹ See <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074> for the final second list of chemicals.

¹⁰ <http://www2.epa.gov/endocrine-disruption>

6 Interim Registration Review Decision

In accordance with 40 CFR Sections 155.50, 155.56 and 155.58, the agency is issuing this Interim Registration Review Decision document. Except for the EDSP component of the homopolymer registration review case, the agency has made the following interim decision that no additional data and no further risk assessments are required. Based on the assumption of no exposure to humans and non-target organisms, no additional data are needed and no risk assessments are planned. The agency has made a “no effect” finding based on lack of potential exposure for endangered species (see Section 4.1).

7 Next Steps

A Federal Register Notice will announce the availability of this Interim Registration Review Decision for homopolymer. The final decision on the registration review for homopolymer (case 5024) will occur after an EDSP FFDCA section 408(p) determination is made. See the estimated timeline for the completion of homopolymer registration review in Table 2.

8 References

Breithaupt, James. May 5, 2015. Review of Modified Activated Sludge Respiration Inhibition Study (OCSPP 850.3300) for Homopolymer. MRID 49437513, D427116

Ciba (year unknown). Flocculation Theory and Application.
http://www.siltstop.com/pdf/flocculation-theory_application.pdf

Hess, C.E., Naik, K.N., Paquin, T.J., and Rose, S.J. February 27, 2003. Topcoat compositions, substrates containing a topcoat derived therefrom, and methods of preparing the same. Publication Number: WO2003016045 A1, Application Number: PCT/US2002/026136.
<http://www.google.com/patents/WO2003016045A1?cl=en>

MRID 42618401. Oslosky, S. (1992) Product Chemistry: Poly (N,N-dimethyl diallyl ammonium chloride): Lab Project Number: DMDAAC. Unpublished study prepared by Calgon Corporation. 8 p.

Park, S.H. April, 2008. Effect of Amine-Based Water Treatment Polymers on the Formation of N-Nitrosodimethylamine (NDMA) Disinfection By-Product. Georgia Institute of Technology.
https://smartech.gatech.edu/bitstream/handle/1853/22549/park_sanghyuck_200805_phd.pdf?sequence=1

Pesticide Action Network (PAN). 2014. Diallyl dimethyl ammonium chloride polymers.
http://www.pesticideinfo.org/Detail_Chemical.jsp?Rec_Id=PC35969

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U.S. Environmental Protection Agency (EPA). 2002. ECOTOX User Guide: ECOTOXicology Database System. Version 3.0. Available: <http://www.epa.gov/ecotox/>

U.S. Environmental Protection Agency (EPA). 2012. EPI-Suite 4.11.
<http://www.epa.gov/oppt/exposure/pubs/episuitedi.htm>

U.S. Environmental Protection Agency. High Production Volume Information System (HPVIS).
<http://www.epa.gov/hpvis/>

Appendix A Toxicology Profile

Acute Toxicity for Product Labeling

As listed in Table 6, homopolymer is a moderate dermal irritant (Category III) and is in Category III for acute oral toxicity and Category IV for acute dermal toxicity based on guideline studies. It is likely a moderate eye irritant (Category III). However, guideline acute studies are not available for acute inhalation acute eye irritation and dermal sensitization.

Table 6 – Acute Toxicity Studies for Homopolymer

Guideline No./ Study Type	MRID No.	Results	Toxicity Category
870.1100/ Acute oral toxicity	42534004	LD50 = 4,100 mg/kg for male and female rat	III
870.1200/ Acute dermal toxicity	42534005	LD50 ≥ 20,000 mg/kg for male and female rabbit	IV
870.1300/ Acute inhalation toxicity	NA	No acceptable Guideline study. This study is considered as a data gap.	Unknown
870.2400/ Acute eye irritation	42534006	Eye irritation at 24 hours after treatment and clearing in 7 days.	III
870.2500/ Acute dermal irritation	42534007	Moderate irritation at 72 hours on New Zealand Albino Rabbits	III

Note: N/A=Not available

Subchronic Toxicity

For subchronic oral toxicity, the database includes four studies:

- Roper, J.M. (2009) A 90-day oral (drinking water) toxicity study of 2-Methyl-1,2-benzisothiazolin-3-one Technical in rats. WIL Research Laboratories, LLC, Ashland, OH, USA. WIL-91057, November 9, 2009. MRID 48251534. Unpublished.
- Trautwein and Drommer. (1976). 13 Weeks Oral Toxicity Feeding Study with Monomer in Rats. International Bio-Research, Inc. Unpublished.
- Trautwein and Drommer. (1976). 13 Weeks Oral Toxicity Feeding Study with Cat Flocc-T in Rats. International Bio-Research, Inc. Unpublished.
- Tegeris, A.S. (1976). DADM – Ninety-Day Feeding Study to Dogs. Pharmacopathics Research Laboratories, Inc. Laurel, MD. 20810. Sponsored Report No. 76-57. July 2, 1976. Unpublished.

Developmental Toxicity

- Adamik, E. R. (1979). Rabbit Teratology Study with Cat-Floe T. Wil Research Laboratories, Inc. Cincinnati, OH 45241. November 29, 1979. MRID 42534016. Unpublished.
- Irvine, L.F.H. and Palmer, K. (1990). Poly(Dimethyl Diallyl Ammonium Chloride) (PDADMAC) Oral (Gavage) Rat Teratology Study. Toxicol Laboratories Limited. Herefordshire, England HR8 1LH. Laboratory Project ID CMA/5/91. November 9, 1991. MRID 48437511. Unpublished.

Reproductive Toxicity

- Adamik, E. R. (1979). Multigeneration Study in Rats with Cat-Floe T. Wil Research Laboratories, Inc. Cincinnati, OH 45241. Laboratory Project ID WIL-1140-77. November 29, 1979. MRID 49437512. Unpublished.

Chronic Toxicity

There is currently no existing chronic toxicity study for homopolymer. Since there is no chronic exposure concern, this is not considered as a data gap.

Carcinogenicity

There is currently no existing cancer study for homopolymer. Since there are existing mutagenicity studies indicating homopolymer is not mutagenic, the absence of a cancer study is not considered as a data gap.

Neurotoxicity

There is no neurotoxicity study in the database for homopolymer.

Mutagenicity

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2. Putman, D.L. (1990). Micronucleus Cytogenetic Assay in Mice - Poly (dimethyldimethyl ammonium chloride). Microbiological Associates, Inc., Rockville, MD 20850. June 21, 1990. MRID 42534014. Unpublished
3. Putman, D.L. (1991). Micronucleus Cytogenetic Assay in Mice. Microbiological Associates, Inc. Bethesda, MD 20816. Laboratory Project ID T9143.122. March 27, 1991. MRID 49437510. Unpublished.

Dermal Absorption/Penetration

There is no dermal absorption study in the database. However, since homopolymer is applied through closed system, there is no occupational exposure.

Immunotoxicity

There is currently no existing immunotoxicity study for homopolymer. However, since there is no exposure concern, immunotoxicity study is not considered as a data gap.

Metabolism

There is no metabolism study available. However, since there is no exposure concern, the absence of a metabolism study is not considered as a data gap.

Appendix B Environmental Fate

Environmental Fate and Transport Properties of Homopolymer

This environmental fate assessment addresses the persistence and mobility of the parent compound homopolymer. Based on the chemical, physical, and environmental fate properties, homopolymer is miscible in water, non-volatile, and stable to hydrolysis and photodegradation, see Table 4. As a flocculant, homopolymer sorbs to organic material, soils and sediment. Additional environmental fate data for homopolymer are not anticipated to be required because, based on the label language, the agency assumes that backflow into surface water will not occur.

Appendix B References

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Appendix C Ecotoxicology Profile

Toxicity to Aquatic Receptors

Freshwater Fish

Table 7 – Freshwater Fish and Amphibian Toxicity Data

Species	Test Material (% a.i.)	Toxicity Endpoint ^B Value	Toxicity Category	MRID/ Study Classification/ Comments
Rainbow trout (<i>Oncorhynchus mykiss</i>)	VeliGon L-M (19.8%)	96-h LC ₅₀ = 0.077 ppm ai 95% CI = 0.59-0.11 ppm ai Probit slope = NA NOAEC = Not determined	Very highly toxic	44148402/ Acceptable
Fathead minnow (<i>Pimephales promelas</i>)	VeliGon L-M (19.8%)	96-h LC ₅₀ = 0.26 ppm ai 95% CI = 0.17-0.48 ppm ai Probit slope = NA NOAEC = Not determined	Highly toxic	44148401/ Acceptable
Rainbow trout (<i>Oncorhynchus mykiss</i>)	VeliGon CL-M (39.8%)	96-h LC ₅₀ = 0.066 ppm ai 95% CI = 0.043-0.12 ppm ai Probit slope = NA NOAEC = 0.043 ppm ai	Very highly toxic	44148405/ Acceptable
Fathead minnow (<i>Pimephales promelas</i>)	VeliGon CL-M (39.8%)	96-h LC ₅₀ = 0.22 ppm ai 95% CI = 0.19-0.26 ppm ai Probit slope = 5.4 NOAEC = 0.11 ppm ai	Highly toxic	44148404/ Acceptable

Freshwater Invertebrates

Table 8 – Freshwater Invertebrate Toxicity Data

Species	Test Material (% a.i.)	Toxicity Endpoint ^B Value	Toxicity Category	MRID/ Study Classification/ Comments
Waterflea (<i>Daphnia magna</i>)	VeliGon L-M (19.8%)	48-h EC ₅₀ = 0.075 ppm ai 95% CI = 0.059 – 0.11 ppm ai Probit slope = NA NOAEC = not determined	Very highly toxic	44148403/ Acceptable
Waterflea (<i>Daphnia magna</i>)	VeliGon (39.8%)	48-h EC ₅₀ = 2.1 ppm ai 95% CI = 1.8 – 2.6 ppm ai Probit slope = NA NOAEC = 0.50 ppm ai	Moderately toxic	156044/ Supplemental

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